DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 8 2006

Mr. John Kapitan
Director of Regulatory Affairs and Quality
Altiva Corporation
9800-I Southern Pines Boulevard
Charlotte, North Carolina 28273

Re: K053070
Trade Name: Contour II Spinal System
Regulation Number: 21 CFR 888.3070 (b) (1)
Regulation Name: Pedicle Screw Spinal System
Regulatory Class: II
Product Code: MNH, MNI, KWQ, KWP
Dated: December 1, 2005
Received: December 2, 2005

Dear Mr. Kapitan:

This letter corrects our substantially equivalent letter of February 13, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053070

Device Name: CONTOUR II™ Spinal System

Indications for Use:

The CONTOUR II™ Spinal System is intended for noncervical, pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

In addition, the CONTOUR II™ Spinal System is intended for skeletally mature patients with severe spondylolisthesis (Grade 3 and 4) of the L5-S1 vertebra, who are receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine (L3 and below), with removal of the implants after the attainment of solid fusion.

The CONTOUR II™ Spinal System (KWP) is also intended for use as a posterior noncervical, nonpedicle system indicated for degenerative disc disease which is defined as back pain of dicogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthosis, or revision of failed fusion attempts.

When used as an anterior fixation system, the CONTOUR II™ Spinal System (KWQ) is indicated for patients with degenerative disc disease which is defined as back pain of the discogenic origin with degeneration of the disc confirmed by history and radiographic studies, spondylolisthesis, fracture, spinal stenosis, spinal deformities such as scoliosis, kyphosis, lordosis, tumor, pseudoarthosis, or revision of failed fusion attempts.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

n Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

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510(k) Number_____

FEB 1 3 2006

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

I. **DATE PREPARED:** 12/07/05

II. **SUBMITTER:**
Altiva Corporation
9800 Southern Pines Blvd.
Suite I
Charlotte, NC 28273

III. **CONTACT PERSON:**
John Kapitan
Director of Regulatory Affairs & Quality Assurance

IV. **TRADE/PROPRIETARY NAME:** CONTOUR II™ Spinal System

V. **DEVICE CLASSIFICATION:**
Orthosis, Spinal Pedicle Fixation, (MNI) per 21 CFR 888.3070
Pedicle Screw Spinal System, (MNH) per 21 CFR 888.3070
Spinal Intervertebral Body Fixation Orthosis, (KWQ) per 21 CFR 888.3060
Spinal Interlaminal Fixation Orthosis, (KWP) per 21 CFR 888.3050

VI. **PREDICATE DEVICES:**
Arcan Orthopedics, Contour Spinal Fixation System (K971457)
Class II
Decision Date: July 16, 1997
(and)
U & I Corporation, Optima Spinal System (K031585)
Class II
Decision Date: June 27, 2003
(and)
Ultium Spinal Plating System, Altiva Corporation (K962784)
Class II
Decision Date: October 2, 1996

VII. **SUBSTANTIAL EQUIVALENCE CONCLUSIONS:**
Altiva concludes that the intended use for the Altiva CONTOUR II™ Spinal System is the same as that of the predicate device, and that the technological characteristics demonstrate that they are equivalent to the predicate device.
Thus, this premarket notification has demonstrated substantial equivalence.

VIII. **DEVICE DESCRIPTION:**

The CONTOUR II™ Spinal System is an anterior / posterior spinal fixation system consisting of Pedicle screws, Stem Clamps, C-Clamps, Set screws, L and straight connecting rods as well as a transverse (cross) linking mechanism. The CONTOUR II™ implant components are fabricated from titanium alloy (Ti-6AI-4V ELI) that conforms to ASTM F 136. Various sizes of these implants are available.

IX. **MATERIALS:**

All components are manufactured from Ti-6AI-4V ELI per ASTM F136-02 implant grade titanium alloy.

X. **INDICATION FOR USE:**

The CONTOUR II™ Spinal System is intended for noncervical, pedicle fixation to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine, including degenerative spondylolisthesis with objective evidence of neurological impairment; fracture; dislocation; scoliosis; kyphosis; spinal tumor; and failed previous fusion (pseudarthrosis).

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XI. **SAFETY INFORMATION:**

Only surgeons trained and experienced in spinal decompression and bone grafting techniques should use the Altiva CONTOUR II™ Spinal System. In addition, thorough familiarization with the implants, instrumentation, and surgical technique is essential. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

XII. **CONCLUSION [21 CFR: 807.92(b)(3)]**

Altiva Corp. believes sufficient information is included to reach a determination of substantial equivalence. We conclude that the subject device is as safe and effective.